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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,465	04/01/2004	Sonia Moreno-Lopez	NHL-NP-45	8524

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,465	MORENO-LOPEZ ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) *21-28 and 32-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response received on 1/22/07 has been entered. Claims 1-20 have been canceled and new claims 21-40 have been added. Claims 21-40 are currently pending in the instant application.

Newly submitted claims 21-28 and 32-40 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: the original claims were drawn to vaccines comprising a DNA expression constructs, not methods of using DNA expression constructs. While previously pending claims 1-16 were drawn to "use" of a DNA expression construct, the previous office action clearly indicated that "use" claims, such as previous claims 1-16, are not considered proper method or process claims as the claims contain no actual method steps. It was further noted in the 112 second rejection of these claims that as the vaccine product claims, claims 17-20, indicate that the vaccine comprises the DNA expression construct of, for example, claim 10, it appeared that the applicant intended to claim the DNA expression construct of claim 10 as a product, and not as a method. As such, no proper methods were in fact claimed in the previous claim set. It is further noted that previous office action clearly indicated that despite the indefiniteness of the previous claims, in the interests of compact prosecution, search and examination of the previous claims would be based on products comprising a DNA expression construct or vaccine comprising a DNA expression construct, see page 8, first paragraph, of the previous office action. Had the original claim set included methods of vaccinating as now claimed in claims 21-28 and 32-40, these claims would have been subject to restriction. Specifically, while the vaccines comprising a DNA expression construct and the

methods of vaccinating a living being are related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the vaccines can be used to transfect cells in vitro in tissue culture and further used to produce the antigen in vitro. As such, the search and examination for the vaccine product, and the method of vaccinating a living being is not coextensive and it would place an undue burden on the examiner to search and examine all inventions together. Therefore, because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, different classification and different search requirements, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-28 and 32-40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 29-31 are currently under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office action.

Priority

The previous office action acknowledged applicant's claim for foreign priority based on applications filed in Germany on October 2, 2001 or November 12, 2001, but noted that certified copies of the DE 101 48 697.9 or DE 101 56 678.6 applications as required by 35 U.S.C. 119(b) had not been provided. In response, the applicant provided a certified copy of DE 101 56 678.6 in German. However, for DE 101 48 697.9, the office has only received a single cover page. A complete certified copy of DE 101 48 697.9 is required to fully comply with 35 U.S.C. 119(b).

Specification

The objection to the abstract of the disclosure is withdrawn in view of applicant's submission of a new abstract which does not contain improper legal language.

The objections to the disclosure for informalities on pages 28 and 29 are withdrawn in view of applicant's amendment to these sections.

Nucleic acid and/or Amino acid Sequences

Applicant's amendment to the specification and claim amendments places this application in compliance with the requirements of 37 CFR 1.821 through 1.825.

Double Patenting

The provisional rejection of claims 1, 7-11, and 17-20 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/816,591, hereafter referred to as the '591 application, is maintained over new claims 29-31 over new claims 22-23 of the copending '591 application.

The applicant argues that the cancellation of claim 1, 7-11, and 17-20 and submission of new claims renders the present rejection moot as the new claims are patentably distinct from the claims of the '591 application. This is not agreed. The claims currently pending in the copending application 10/816,591 continue to recite a vaccine composition which is a species of the instant broader claims. The instant claims are broadly drawn to a vaccine comprising a DNA expression construct to elicit a Th1 type immune response. The '591 claims are more narrow and drawn specifically to vaccines comprising the constructs for immunization against leishmania, and further limit the construct coding sequence to encoding the p36 LACK antigen and the oligopeptide to PKKKRKV. As such, the '591 claims represent a species of the instant broader claims. It is well established that a species of a claimed invention renders the genus obvious. *In re Schaumann* , 572 F.2d 312, 197 USPQ 5 (CCPA 1978). Therefore, the '591 claims continue to render the instant claims obvious.

The rejection of record therefore stands.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The rejection of 1-6, and 10-16 under 35 U.S.C. 112, second paragraph and 35 U.S.C. 101 is withdrawn in view of the cancellation of these claims.

The rejection of claims 1-20 under 35 U.S.C. 112, second paragraph, for indefiniteness is withdrawn in view of the cancellation of these claims.

Claim Rejections - 35 USC § 102

The rejection of claims 1-5, 7-15, and 17-20 rejected under 35 U.S.C. 102(a) as being anticipated by Schirmbeck et al. (June 2001) J. Mol. Med., Vol. 79, 343-350, is withdrawn over canceled claims 1-5, 7-15, and 17-20 and maintained over new claims 29-31. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the rejection of record as discussed in detail below.

The applicant argues that Schirmbeck et al. does not teach the limitations of the new claims. This is not agreed. Schirmbeck et al. teaches a minimal expression construct (MIDGE) comprising covalently closed linear DNA that contains only an HBsAG coding sequence operably linked to CMV promoter and polyA termination sequence where the linear ends are linked by short single stranded loops of DNA, and wherein the construct is further covalently linked to the NLS oligopeptide PKKKRKVEDPYC (Schirmbeck et al., page 345, Figure 1 B.3). Schirmbeck et al. also teaches a vaccine comprising this construct (Schirmbeck et al., page 343).

The applicant also argues various limitations of the withdrawn method claims. In so far as vaccine claims under examination recite the intended use of the vaccines for intradermal injection to elicit a type 1 cellular mediated immune response against intracellular infections, the applicant is reminded that the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that,".. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02). A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure or composition, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. *In re Hirao* , 535 F.2d 67, 190 USPQ 15 (CCPA 1976); *Kropa v. Robie* , 88 USPQ 478, 481 (CCPA 1951). As such, by teaching the exact structural elements of the claims as written, Schirmbeck et al. anticipates the instant claims.

The applicant further argues that Schirmbeck et al. does not render the instant invention obvious. However, the instant rejection is a rejection under 35 U.S.C. 102 for anticipation, not a 103 rejection for obviousness. As such, applicant's arguments regarding obviousness are irrelevant to the instant rejection.

Thus, the rejection of record stands.

The rejection of claims 1, 7-11, and 17-20 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,451,593 (2002), hereafter referred to as Wittig et al., is withdrawn over canceled claims 1-5, 7-15, and 17-20, and maintained over new claims 29-31. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the rejection of record as discussed in detail below.

The applicant argues that Wittig et al. does not teach the limitations of the new claims. This is not agreed. Wittig et al. teaches dumbbell shaped DNA expression constructs comprising covalently closed linear DNA that contains only a coding sequence operably linked to a promoter and polyA termination sequence where the linear ends are linked by short single stranded loops of DNA, and wherein the construct is further covalently linked to a peptide which directs transport of the construct across a cell's endosome or into the nucleus (Wittig et al., claims 1-11, and columns 5-8)). Wittig et al. also teaches that the coding sequence can encode various cytokines, including Th1 cytokines such as IL-12, and methods of administering the constructs including intradermal administration (Wittig et al., columns 1, 8, and 13). Wittig et al. also teaches a vaccine comprising this construct (Wittig et al., column 8). Please note that while the new claims recite that the construct encodes an "antigen", the claims do not place any limitation on the type of "antigen" encoded by the construct. Any protein capable of being recognized by either B cells, T cells, or complement qualifies as an "antigen". As such, the cytokines disclosed by Wittig et al. qualify as an "antigen".

The applicant also argues various limitations of the withdrawn method claims. In so far as vaccine claims under examination recite the intended use of the vaccines for intradermal injection to elicit a type 1 cellular mediated immune response against intracellular infections, the

applicant is reminded that the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that,".. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02). A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure or composition, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. *In re Hirao* , 535 F.2d 67, 190 USPQ 15 (CCPA 1976); *Kropa v. Robie* , 88 USPQ 478, 481 (CCPA 1951). As such, by teaching the exact structural elements of the claims as written, Wittig et al. anticipates the instant claims.

The applicant further argues that Wittig et al. does not render the instant invention obvious. However, the instant rejection is a rejection under 35 U.S.C. 102 for anticipation, not a 103 rejection for obviousness. As such, applicant's arguments regarding obviousness are irrelevant to the instant rejection.

Thus, the rejection of record stands.

Claim Rejections - 35 USC § 103

The rejection of claims 1-4, 6, 10-14, and 16 under 35 U.S.C. 103(a) as being unpatentable over Schirmbeck et al. (June 2001) J. Mol. Med., Vol. 79, 343-350 in view of U.S. Patent No. 6,451,593 (2002), hereafter referred to as Wittig et al., and Liu et al. (2001) Biomacromolecules, Vol. 2, 362-368, is withdrawn in view of the cancellation of these claims. It is further noted that this rejection has not been applied to new claims 29-31 currently under examination as the specific limitation that the oligopeptide comprises YGRKKRRQRRR is not recited in new claims 29-31.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER